UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
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RxUSA WHOLESALE, INC., ALDEN SURGICAL, CO., INC., ATLANTIC BIOLOGICALS, INC., BELL MEDICAL SERVICES, INC., C.O. TRUXTON, INC., HYGEN PHARMACEUTICALS, INC., MEDEX MEDICAL, INC., MEDSOURCE DIRECT, INC., MIKA PHARMACEUTICALS, INC., and STAT PHARMACEUTICALS, INC.,

Plaintiffs,

against

ORDER ADOPTING REPORT AND RECOMMENDATION
06-CV-5086(JS)(AKT)

DEPARTMENT OF HEALTH AND HUMAN SERVICES, U.S. FOOD AND DRUG ADMINISTRATION,

Defendants
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APPEARANCES:

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Scarsdale, New York 10583

For Defendants: Vincent Lipari, Esq.
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SEYBERT, District Judge:

INTRODUCTION

Before this Court is Magistrate Judge A. Kathleen Tomlinson's Report and Recommendation, dated November 30, 2006, regarding Plaintiffs' motion for a preliminary injunction. The Magistrate recommended that this Court preliminarily enjoin the Defendants from implementing certain regulations that were to take

effect on Friday, December 1, 2006. Pursuant to FED. R. CIV. P. 72(b), the Defendants objected to certain parts of the Report and Recommendation, and Plaintiffs responded. Pursuant to 28 U.S.C. § 636(b)(1), this Court reviews de novo those portions of the Report and Recommendation to which Defendants object. Such de novo review does not entirely replace the Magistrate's efforts.

After carefully reviewing Defendants' objections and hearing oral argument on December 4, 2006, this Court adopts in part and modifies in part the Report and Recommendation and grants Plaintiffs' request for a preliminary injunction. For purposes of this Order, familiarity with the facts of the case is presumed. The Court refers the parties to the facts as stated in the Report and Recommendation.

DISCUSSION

Defendants have objected to several parts of the Magistrate's Report and Recommendation. Defendants have challenged the Magistrate's conclusion that Plaintiffs will suffer irreparable harm and have a likelihood of success on the merits. Defendants also raise issue with the Magistrate's factual findings. The Court turns to each of Defendants' objections.

I. Defendants Do Not Deny Plaintiffs Will Be Irreparably Harmed Without An Injunction.

For this Court to issue a preliminary injunction against "government action taken in the public interest pursuant to a statutory or regulatory scheme," the Plaintiffs must show "(i)

irreparable harm absent the injunction and (ii) a likelihood of success on the merits." Freedom Holdings, Inc. v. Spitzer, 408 F.3d 112, 114 (2d Cir. 2005) (citations omitted). A plaintiff satisfies the irreparable harm requirement when it shows that absent a preliminary injunction, it "will suffer 'an injury that is neither remote nor speculative, but actual and imminent,' and one that cannot be remedied 'if a court waits until the end of trial to resolve the harm.'" Id. (citations omitted). Because irreparable harm is "the single most important prerequisite" before a preliminary injunction will issue, Plaintiffs must show first that the injury is "likely" before showing any other requirements. Id.

Defendants attempt to challenge Plaintiffs' claim that they will suffer irreparable harm. However, the Court rejects this argument at the outset because Defendants' argument is circuitous. First, Defendants do not directly address Plaintiffs' claims that they will suffer irreparable harm. Instead, Defendants claim that staying the FDA regulation will not save Plaintiffs from any irreparable harm because the statute - which the FDA regulation "mirrors" - still requires pedigree information back to the manufacturer. Thus, Defendants have essentially acknowledged that Plaintiffs will suffer irreparable harm - it is just a matter of the source of the harm: the PDMA or the FDA regulation.

Accordingly, the Court finds that Plaintiffs have met their burden regarding the irreparable harm prong of a preliminary

injunction. Defendants do not deny Plaintiffs will be irreparably harmed. It simply challenges the source of the harm, which does not change that such harm is bound to occur without a preliminary injunction. The Court adopts that portion of the Report and Recommendation finding that Plaintiffs will suffer irreparable harm.

II. Plaintiffs Have Shown A Likelihood Of Success On The Merits.

The second prong that Plaintiffs must meet for this Court to issue a preliminary injunction is a likelihood of success on the merits. See Freedom Holdings, Inc., 408 F.3d at 114. For purposes of a preliminary injunction, however, this Court need not find with "absolute certainty" that Plaintiffs will succeed on the merits of their claims. Wali v. Coughlin, 754 F.2d 1015, 1025 (2d Cir. 1984) ("A movant . . . need not show that success is an absolute certainty. He need only make a showing that the probability of his prevailing is better than fifty percent. There may remain considerable room for doubt.") Thus, a finding that a plaintiff has more than a fifty-fifty chance of succeeding on the merits of their claims would warrant a finding of a likelihood of success on the merits.

A. Defendants' Arguments

First, Defendants object to the Magistrate's conclusion that the classification fails rational basis review because authorized distributors purchase a significant volume of drugs from

unauthorized distributors and then resell those drugs without a pedigree. (Def.'s Mem. of Law 5.) Second, Defendants also claim the Magistrate erred when she found that it was not rational to believe that Congress intended to create a situation where it was impossible for four thousand unauthorized distributors to comply with the law. (Id. at 6.) Defendants specifically claim that this is a disputed factual issue.

Third, Defendants claim the Magistrate erred when she relied on certain statements made after the Prescription Drug Marketing Act ("PDMA") was passed. (Id. at 8-9.) Specifically, Defendants argue that the Magistrate should have looked solely to facts as they were when Congress enacted the PDMA.

B. The Rational Basis Test & Review Of Administrative Actions

Defendants do not object to the Magistrate's conclusion that a statute must be rationally related to its stated purpose to be Constitutional. A court cannot overturn a statute "unless the varying treatment of different groups or persons is so unrelated to the achievement of any combination of legitimate purposes that we can only conclude that the government's actions were irrational." Kimel v. Fla. Bd. of Regents, 528 U.S. 62, 84, 120 S. Ct. 631, 145 L. Ed. 2d 522 (2000) (quoting Vance v. Bradley, 440 U.S. 93, 97, 99 S. Ct. 939, 59 L. Ed. 2d 171 (1979)). The Court must inquire whether a statute is "rationally related to legitimate [governmental] interest." Vance, 440 U.S. at 97 (quoting Mass. Bd.

of Ret. v. Murgia, 427 U.S. 307, 312, 96 S. Ct. 2562, 49 L. Ed. 2d 520 (1976)).

Defendants also do not object to the Magistrate's conclusion that the FDA's administrative actions are subject to review by the Court under the Administrative Procedure Act ("APA"). (Report at 20.) The FDA's actions may be disturbed only "if arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." 5 U.S.C. § 706(2)(A). "When a court reviews an agency's construction of a statute it administers," a court must determine "whether Congress has directly spoken to the precise question at issue." Chevron, U.S.A., Inc. v. Natural Res. Def. Council, 467 U.S. 837, 842-43, 104 S. Ct. 2778, 81 L. Ed. 2d 694 (1984). "[I]f the statute is silent or ambiguous with respect to the specific issue," a court must determine whether such regulation is "a permissible construction of the statute." Id. at 843.

However, in Bldg. and Constr. Trades Dep't v. Donovan, 543 F. Supp. 1282, 1290 (D.C. 1982), the court preliminarily enjoined an agency from enforcing regulations issued to implement the Davis-Bacon Act. The Donovan court analyzed the new administrative actions with "more exacting vigilance" because the agency was changing a "longstanding administrative position" that had originally been taken contemporaneously with or shortly after the legislation. Id. at 1290.

At the outset, the Court notes that Congress had a rational basis when it required unauthorized distributors to provide pedigree information for the drugs it distributed. The Magistrate, this Court, and both parties agree on this. The PDMA's pedigree requirement is important and necessary in light of Congress's findings that "most of the drugs that were counterfeits, stolen, expired, or obtained through fraud were handled by secondary wholesalers, who were not authorized to distribute that manufacturer's product." H.R. Rep. No. 100-76, at 17 (1987). PDMA's purpose "is to protect American consumers from mislabeled, subpotent, adulterated, expired, or counterfeit pharmaceuticals, which are being dispensed under existing law and practice, and to restore competitive balance in the marketplace." Id. at 6. Accordingly, the Court rejects that portion of the Report and Recommendation that finds the PDMA had no rational basis.

The issue, however, is whether the regulatory scheme created to enforce the PDMA is arbitrary and capricious in light of the FDA's position for the last sixteen years and its findings stated in its various reports to Congress. Defendants do not dispute the Magistrate's finding that both manufacturers and authorized distributors are exempt from the pedigree requirement. (Report at 12.) When the PDMA was first enacted in 1988, the statute read as follows:

> Each person who is engaged in the wholesale distribution of the drugs . . . and who is not an authorized

> distributor of record of such drugs shall provide to each wholesale distributor of such drugs a statement identifying each sale of the drug (including the date of sale) before the sale to such wholesale distributor.

(Drucker Aff. Ex. 1.)

The FDA interpreted this statute as requiring unauthorized distributors to provide pedigree information back to either the manufacturer or the authorized distributor, depending upon from whom the unauthorized distributor purchased the drugs. (Drucker Aff. ¶¶ 14-15; Ex. 6 at 27.) The FDA thus considered the statutory exemptions for manufacturers and authorized distributors from the pedigree requirement when issuing its guidance letter in 1988. The FDA "believed that this [interpretation] was consistent with the legislative history of PDMA, which indicated that Congress intended that the drug pedigree be a written certification fully identifying the source and place from which the drugs were obtained." (Drucker Aff. Ex. 6 at 27 (emphasis added)).

In 1992, Congress amended the PDMA to require unauthorized wholesale distributors to provide pedigree information "identifying each prior sale, purchase, or trade of such drug (including the date of the transaction and the names and addresses of all parties to the transaction)." 21 U.S.C. § 353(e)(1)(A)(b). Neither the statute - as originally written or as amended - specifically or expressly required unauthorized distributors to provide pedigree information all the way back to the manufacturer.

But in 1994, the FDA proposed a new rule requiring the unauthorized wholesale distributors to provide pedigree information for sales all the way back to the manufacturer. See Drucker Aff., Ex. 6 at 27; 21 C.F.R. § 203.50(a) (hereinafter referred to as the "Rule"). In this regard, the Court departs from the Magistrate's finding that the regulation "closely mirrors" what the statute requires. (Report at 21.)

The FDA, however, delayed implementation of the Rule for twelve years. The FDA had reported to Congress that the PDMA pedigree exemption for authorized distributors allowed a "large volume of prescription drugs [to] move through the system without pedigrees, or with incomplete pedigrees, because they [had] passed through an authorized distributor at least once before reaching their retail destination." (Drucker Aff. Ex. 17, DEP'T OF HEALTH AND HUMAN SERVS. U.S. FOOD AND DRUG ADMIN., PRESCRIPTION DRUG MARKETING ACT REPORT TO CONGRESS 9 (2001).) The FDA further found that the exemption "undermines the purpose of the pedigree by allowing for potential gaps in the distribution history." Id.

If the Rule were to go into effect while the exemption for authorized distributors existed, the result would completely defeat the purpose of the PDMA. Pedigree information would not be available for any drugs moving through commerce. Any drugs passing through an authorized distributor would contain no pedigree information due to the statute's exemption. Unauthorized

distributors would be unable to comply with the Rule. They would be unable to provide complete pedigree information for all prior sales up to the manufacturer because - as the FDA has found - most drugs pass at least once through authorized distributors who do not provide pedigree information. And according to Plaintiffs, manufacturers refuse to sell products directly to Plaintiffs so they have no choice but to purchase from authorized distributors. (Report at 2.)

This entire regulatory scheme and the anomalous result that would occur if the Rule went into effect appears arbitrary in light of the FDA's previous position and interpretation of the PDMA. The PDMA's purpose is to protect the American consumer from tainted pharmaceuticals. The pedigree requirement was created to show where wholesale distributors were obtaining their drugs. But the Rule would essentially wipe out all the unauthorized distributors, leaving only authorized distributors who are exempt from the pedigree requirement. So none of the drugs ultimately going to the American consumer would contain pedigree information because the drugs would be provided solely through authorized distributors who are exempt from the pedigree requirement. Accordingly, the Court rejects Defendants' objections to the Magistrate's findings regarding Plaintiffs' likelihood of success on the merits.

To the extent that Defendants object to the Magistrate's

supposed factual findings, Defendants prematurely raise this objection. None of the Magistrate's findings of fact nor this Order's recitation of facts are conclusive. "[F]indings of fact . . . made by a court granting a preliminary injunction are not binding at trial on the merits [because] . . . a preliminary injunction is customarily granted on the basis of procedures that are less formal and evidence that is less complete than in a trial on the merits." Thornburgh v. Am. Coll. of Obstetricians & Gynecologists, 476 U.S. 747, 806, 106 S. Ct. 2169, 90 L. Ed. 2d 779 (1986) (quoting Univ. of Tex. v. Camenisch, 451 U.S. 390, 395, 101 S. Ct. 1830, 68 L. Ed. 2d 175 (1981)). "The purpose of a preliminary injunction is . . . to preserve the relative positions of the parties until a trial on the merits can be held. . . . A party is not required to prove his case in full at a preliminary-injunction hearing." Univ. of Tex., 451 U.S. at 395. The Magistrate simply cited to affidavits and exhibits presented to her at the hearing, none of which suffice for conclusive factual findings. Accordingly, the Court rejects Defendants' objections to the extent they relate to the Magistrate's factual findings or reliance on facts stated in the parties' affidavits or exhibits.

III. The Preliminary Injunction Serves The Public Interest.

Lastly, the Court raises one final issue not discussed in the Report. When a preliminary injunction implicates public interests, a court should consider the balance of such interests in

deciding if "a plaintiff's irreparable injury and probability of success on the merits warrants injunctive relief." Brody v. Vill. of Port Chester, 261 F.3d 288, 290 (2d Cir. 2001). This Court believes a preliminary injunction in this instance benefits the public interest.

Since passage of the PDMA in 1988, both authorized and unauthorized wholesale distributors have been complying with the PDMA by providing pedigree information back to the authorized distributors from whom the drugs were purchased. (Report at 16.) By granting Plaintiffs' motion for the preliminary injunction, this Court simply maintains the status quo and the current practice in the industry. The Court enjoins the Defendants from implementing the Rule that would require unauthorized distributors to provide pedigree information about the transactions of their drugs all the way back to the manufacturer. This maintains the positions of the parties that have been in effect for the last eighteen years since passage of the PDMA.

To allow the Rule to go into effect may "prevent over 4,000 smaller, unauthorized distributors from distributing drugs to their customers and may put them out of business . . . ." Drucker Aff. Ex. 8 at 25640. This in turn may ultimately lead to "underserved" markets and consumers for prescription drugs. Id. Because of these concerns regarding the four thousand unauthorized distributors and potentially underserved markets and consumers, the

FDA continued to delay implementation of the Rule. Id. at 25641. Specifically, the "Commissioner of Food and Drugs [found] that this delay of [the Rule's] effective date is in the public interest." Id. And of course, while the pedigree requirement is not perfect with its current exemptions, at least some information is provided as to where some drugs have been obtained. This somewhat comforts the American public that the purpose of the PDMA - to protect American consumers from counterfeit, expired or mislabeled drugs - is being met by tracking where some drugs are obtained. Without this, only authorized distributors would provide drugs to the public and these distributors would not need to provide any information as to where they obtained their drugs.

The Court agrees that maintaining the status quo and enjoining the FDA from implementing the Rule is in the public interest. This Rule may drastically change how prescription drugs are distributed in this country and ultimately affect the cost to the consumer in terms of insurance premiums and prescription drugs. If the statute and Rule are found to be Constitutional, no prejudice results to Defendants in waiting a little bit longer to implement the Rule, especially in light of the fact that Defendants have delayed enforcement for the last twelve years.

CONCLUSION

Based on the reasons above, the Court adopts in part and modifies in part Magistrate Judge A. Kathleen Tomlinson's Report and Recommendation. The Court preliminarily enjoins Defendants from implementing 21 C.F.R. § 203.50(a) on December 1, 2006.

SO ORDERED.

/s/ JOANNA SEYBERT
Joanna Seybert, U.S.D.J.

Dated: Central Islip, New York
December 8, 2006